

DRAFT

COMMUNICATION FROM THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES TO THE TRIPS COUNCIL

CONCEPT PAPER FOR APPROACHES RELATING TO PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

I. Introduction

1. The Doha Declaration on the TRIPs Agreement and Public Health recognises in its paragraph 6 that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. Therefore, the Declaration instructs the TRIPs Council to find an expeditious solution to this problem before the end of 2002.

2. The European Communities and their Member States (hereinafter “the EC”) are committed to co-operating with the other WTO Members in view of finding an expeditious solution to the issue invoked under paragraph 6 of the Declaration. The EC take the view that Members should endeavour to reach an agreement on a solution before the end of 2002.

3. In this Communication, the EC briefly examine the problem invoked in paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health and explore possible options for a solution.

4. As a preliminary remark, the EC wish to point to two important aspects. First, even when manufactured under a compulsory licence, medicines may still be unaffordable for certain segments of the population in poor countries. Production of medicines, even by a manufacturer other than the patent holder, always has a cost, and these manufacturers will seek a reasonable return on investment to make it economically viable and sustainable. However, for the poorest populations, even the lowest possible price of generic medicines or medicines manufactured under a compulsory licence remains unaffordable. Second, any solution that may result from the current process in the TRIPs Council will not provide the universal panacea of solutions for the problem of access to medicines. As the EC have already emphasised, improving access to medicines requires a mix of complementary measures in different areas (public financing of drugs’ purchases; strengthened health care systems and infrastructure to distribute, deliver and monitor drugs’ usage; information and education and increased research and development). The discussion within the TRIPs Council should not overshadow these aspects and efforts to make medicines available at affordable prices in a number of international fora, such as in the context of the Global Fund to fight HIV/AIDS, tuberculosis and malaria (GFATM).

II. The problem

1. From a legal point of view

5. During the previous discussions within the TRIPs Council on the link between the TRIPs Agreement and public health, it had been argued that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement with regard to patented pharmaceuticals.

6. It is true that for such Members, the right granted by Article 31 TRIPs is of no practical use when, in reality, there is no manufacturer to which such licences can be granted. This can, under certain circumstances, constitute a handicap, especially in view of obtaining medicines at affordable prices in view of supplying them to the population.

7. By virtue of the principle of territoriality of patent protection, these Members can not grant a compulsory licence to a foreign manufacturer, because the patent covering the product in the other country is independent from the patent in the former country. Of course, any WTO member can grant a compulsory licence to *import* a patent protected product from other countries. There is however no guarantee that sufficient supply will be available at favourable conditions.

8. These Members could of course rely on *another* Member to issue a compulsory licence to one of its manufacturers in view of exporting the production under that compulsory licence to the Member without manufacturing capacity. In practice, such solution would in most cases not be workable because of the limitation under 31(f) of the TRIPs Agreement, which stipulates that “a predominant part” of the production under a compulsory licence must remain on the domestic market of the Member granting the licence. Fulfilling this requirement would be impossible if there is no or only little demand on that domestic market, in which case that market cannot absorb a predominant part of the production. Moreover, in situations of national emergency or other cases of extreme urgency precious time would be lost.

9. Recent events show that the threat to issue compulsory licences for drugs may, under certain circumstances, be instrumental in negotiating significant price cuts on essential medicines. An explicit or implicit threat to resort to compulsory licensing by a government, which can rely on domestic capacity to engage into massive production, can be a factor for the patent holder to agree on a substantial price cut. Arguably, countries with no or limited pharmaceutical manufacturing capacity do not dispose of that kind of leverage. This may put them in a less favourable negotiating position. Therefore, the EC agree that this is a relevant issue for discussion.

2. Patent situation in developing and least-developed country Members

10. It is a fact that a vast majority of developing and least-developed country Members are characterised by a manifest lack of manufacturing capacities for pharmaceuticals, although there are some exceptions.

11. It should be borne in mind that the ability to issue a compulsory licence depends on whether or not a certain drug is patented, which pre-supposes that the country has a patent legislation. Therefore, the first element to take into account in assessing the problem at stake is the patent situation of pharmaceuticals in developing and least-developed country Members.

12. Whilst most developing country Members do provide for patent protection for pharmaceutical products, a number of them¹ has opted for the additional transition period of Article 65:4 of the TRIPs Agreement, allowing them to exclude pharmaceuticals from product patentability until 1 January 2005.

13. As far as least-developed country Members are concerned, Article 66:1 of the TRIPs Agreement provides that the transition period for implementing the TRIPs Agreement runs until 1 January 2006, while specifying that the TRIPs Council shall, upon duly motivated request by a least-developed country Member, accord extensions of this period. At the Doha Ministerial Conference, it was agreed under paragraph 7 of the Doha Declaration on TRIPs and Public Health that least-developed country Members will not have to implement or apply patent protection and data protection for drugs before 1 January 2016, and the TRIPs Council is instructed to take necessary action to give effect to this pursuant to Article 66:1 of TRIPs.

14. It has been argued in this context that patent protection for pharmaceuticals does not exist in any least-developed country Member (and that, therefore, 31 (f) TRIPs, does not pose any problem). This does not correspond to the truth : some least-developed country Members do provide for such protection. For example, all 15 Members² of the “Organisation Africaine de la Propriété Intellectuelle” (OAPI), most of which are least-developed countries, do provide for patent protection for pharmaceuticals. The same applies to the 14 signatories of the Harare Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property (ARIPO)³. At the other end of the spectrum, a few least-developed countries have no patent law at all. Account also needs to be taken of the fact that where patent protection is available, patents are not necessarily always applied for. As a result, many medicines, but not necessarily all of them remain unpatented in the majority of least-developed countries. In principle, these countries are free to import generic versions of pharmaceuticals that are still patented in other countries. In practice, however, it is difficult to find reliable sources for a sufficient, sustainable and affordable supply for these medicines.

15. Evidence shows that patents on antiretrovirals, for instance, are in force in several countries of Sub-Saharan Africa. They appear to be concentrated in countries where pharmaceutical markets are relatively large, such as South Africa or Kenya. In South Africa, for example 13 out of 15 antiretroviral treatments are patented.

¹ Cuba, Egypt, India, Madagascar, Pakistan, Qatar, United Arab Emirates.

² **Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Cote D'Ivoire, Gabon, Guinea, Guinée-Bissau, Mali, Mauritania, Niger, Senegal.** LDC Members are in bold.

³ Botswana, **The Gambia,** Ghana, Kenya, **Lesotho, Malawi, Mozambique, Sierra Leone, Sudan,** Swaziland, **Tanzania, Uganda, Zambia** and Zimbabwe. LDC Members are in bold.

16. We are far from a situation where all pharmaceuticals are patented in all WTO Members, but, at the same time, it would be false to claim that patents are not a factor to take into account at all in the light of concerns of developing and least-developed country Members.

17. It should be borne in mind that some developing and several least-developed country Members have the legal (but not necessarily the actual) possibility to manufacture generic versions of pharmaceuticals that are still patented in industrialised countries, or at least to import them from Members which are not yet under an obligation to provide patent protection to pharmaceuticals. There are a few developing countries that today combine legal and actual manufacturing capacity for generic pharmaceuticals, and are able to manufacture them also *for export* to Members where these drugs are not patented or to Members which have issued a compulsory licence for their import. The first category of countries will lose that capacity as from 2005 as a result of Article 65:4 of the TRIPs Agreement. So, it is evident that, where the possibility still exists to manufacture or import generic versions of drugs that are still under patent in other countries, this possibility will fade out in 2005.

18. Therefore, the EC are willing to consider solutions with a view to solving the problem identified in paragraph 6 of the Declaration on the TRIPs Agreement and Public Health.

III. Options for a solution

19. At this stage, the discussion could focus on two possible avenues for a solution:

1) an amendment to Article 31 of the TRIPs Agreement in order to carve out an exception to Article 31(f) for exports under compulsory licences, under certain conditions, of products needed to combat serious public health problems; or

2) an interpretation of the limited exceptions clause of Article 30 of the TRIPs Agreement in a way to allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems;

III.1 Possible amendment of Article 31 of the TRIPs Agreement

20. A first possibility that could be considered by the TRIPs Council is the introduction of an exception to the principle stated in Article 31(f) of the TRIPs Agreement that compulsory licences “shall be authorised predominantly for the supply of the domestic market of the Member authorising such use”.

21. Such an exception clause would state that Article 31(f) does not apply to compulsory licences granted in view of supplying a poor country with a product needed to address serious public health problems. An exception to Article 31(f) already exists under Article 31(k), which states that the limitation of Article 31(f) does not apply to compulsory licences issued to remedy practices where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

22. However, such an exception clause would need to be carefully crafted and assorted with the necessary conditions to avoid abuses and trade diversions. The objective of the exception clause would be to cover exceptional circumstances, when serious health problems arise in small economies lacking a sufficient production capacity for pharmaceuticals.

23. It is indeed the EC's view that the use of this exception should under no circumstances be diverted from its objective, i.e. to provide pharmaceuticals and other health products to countries in need of such products. Therefore, the necessary safeguards need to be provided with a view to avoiding that production pursuant to the proposed exception is diverted from its destination. Any abuse of it could open the door to massive circumvention of intellectual property rules, which would seriously impair the legal security of right holders and undermine the basic principles of the TRIPs Agreement.

24. Therefore, two important conditions to be further discussed and refined are :

- the need to provide safeguards against exports to countries which do not face serious public health problems;
- the need to provide safeguards against re-exportation from the country of destination, especially to rich country markets, in view of avoiding "black markets" for the products concerned.

25. If the exception is not satisfactorily tied by such conditions, there could be a risk that any abuse of this exception would undermine confidence in the TRIPs Agreement as well as in initiatives taken to supply medicines at affordable prices to poor countries and weaken industry support for any subsequent initiative on access to medicines.

26. The advantage of the approach considered here is that there would be a clear ground, in the TRIPs Agreement itself, to export to a small or least-developed country, under a compulsory licence, products needed in view of addressing serious public health problems, whatever the patent situation of the product concerned in the Member in question.

III.2 Possible interpretation of Article 30 of the TRIPs Agreement

27. Another approach would consist of interpreting Article 30 of the TRIPs Agreement in a way that would allow a Member to introduce a specific exception in its law in view of supplying another country which has granted a compulsory licence for the importation of a specific pharmaceutical product.

28. To this end WTO Members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPs Agreement, provide that the manufacture, on its territory, of a patented product, without the authorisation of the right holder, is lawful when the tolerated production is meant to supply another country which has granted a compulsory licence for the import and sale of the product concerned in its territory in order to deal with a serious public health problem.

29. The basic principle of such a construction would be that the juxtaposition of distinct legal situations in two distinct Members would allow a country without sufficient manufacturing capacity to give full effect to a compulsory licence on its territory. On the one hand, we would have a country without a sufficient manufacturing capacity for pharmaceuticals which, pursuant to Article 31 of the TRIPs Agreement, grants a compulsory licence to an economic operator, authorising him to import and sell a patented pharmaceutical on its territory. On the other hand, we have another Member which would make use of a limited exception under its patent law (based on Article 30 of the TRIPs Agreement), which allows manufacturers designated by the beneficiary of the compulsory licence, to manufacture that product, without the authorisation of the patent holder, for export to the first Member when a number of conditions are fulfilled.

30. The advantage of this approach would be that it could fit within the flexibility offered by the existing TRIPs Agreement, without there being a need to go through a procedure to amend any of its provisions. It would be left to each Member's discretion to decide whether or not it would incorporate the Article 30-based exception in its legislation.

31. As we indicated for the first option, it should be understood that use of this option can only be considered if it is assorted with the necessary safeguards that the exception can only be resorted to in view of supplying the Member which needs the product concerned. Hence the need for conditions to make sure that the quantities produced in the country of manufacture do not exceed the quantity needed by the country of destination and to avoid that production pursuant to the proposed exception is diverted from its destination. These conditions would, at the minimum, be that 1) the entirety of the production allowed under the Article 30-exception must be imported to the Member having granted the licence for the sole purpose of the compulsory licence and 2) the product will be commercialised or distributed solely in the Member having granted a licence and not be re-exported from the first Member. Furthermore, both Members involved in the activities outlined above should take the necessary measures to avoid trade diversion.

32. These conditions are not designed to create burdensome new obligations for Members, but stress the need for the Members involved to take the necessary measures within the context of their existing administrative procedures, notably in the area of customs.

33. Finally, the EC would like to stress that any interpretation agreed upon on the basis of Article 30 has to be in full conformity with the relevant other provisions of the TRIPs Agreement, and in particular its Article 27.1, the general principles of treaty interpretation as laid down in the Vienna Convention (as specified in paragraph 5(a) of the Doha Declaration on the TRIPs Agreement and Public Health), as well as with relevant rulings by WTO Panels and the Appellate Body.

34. The EC welcome any comments other Members may have.